



Please cancel claims 9 and 19 without prejudice.

Remarks

Applicant would like to thank the Examiner for the telephone interview held on November 18, 2002, in which the present amendment was discussed.

Claims 1-12, 14-32, 35, 39, 41, 42, 44, and 45 are pending in the application. Claims 1-12, 14-32, 35, 39, 41, 42, 44, and 45 stand rejected. Claims 1-8, 10-12, 14-18, 20, 29, 30, 32, 39, 41, 42, and 44 are amended as above. Claims 9 and 19 have been canceled, and new claim 46 has been added. Support for claim 46 can be found on page 7, lines 23-24, and on page 8, lines 10-15, of the Specification. No new matter is added to the Specification by these changes. Applicant respectfully requests reexamination and reconsideration of the case, as amended. Each of the rejections levied in the Office Action is addressed individually below.

I. Rejection under 35 U.S.C. §112, first paragraph, for lack of written description.

Claims 1-12, 14-32, 35, 39, 41, 42, and 45 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the Application was filed, had possession of the claimed invention. Applicant has amended the claims to recite "an endosomal lysing *polymer* comprising an endosomolytic agent and one or more hydrolyzable functional moieties selected from the group consisting of ortho-esters, hydrazones, and cisactonyls...." As noted by the Examiner on page 5 of the last Office Action, the as-filed Specification provides sufficient description of an endosomal lysing polymer comprising an endosomolytic agent and one or more hydrolysable functional moieties selected from the group consisting of ortho-esters, hydrazones, and cis-actonyls, wherein said polymer is capable of effecting the lysis of an endosome in response to a change in pH. Given the support as found in the Specification and as noted by the Examiner, Applicant requests that the rejection be removed.

II. Rejection under 35 U.S.C. §112, first paragraph, for lack of enablement. Claims 1-45 are rejected under 35 U.S.C. §112, first paragraph, on the ground that the Specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly





connected, to make and use the invention commensurate in scope with these claims. Applicant submits that the presently amended claims are enabled by the as filed Specification. As noted by the Examiner beginning at the bottom of page 10 of the last Office Action, the Specification provides reasonable enablement for an endosomal lysing polymer comprising an endosomolytic agent and one or more hydrolysable functional moieties selected from the group consisting of ortho-esters, hydrazones, and cis-actonyls, wherein said polymer is capable of effecting the lysis of an endosome in response to a change in pH. Therefore, Applicant submits that the amended claims, which recited an "enodosomal lysing polymer," are enabled by the as-filed Specification and requests that the rejection be removed.

Rejection under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 32 is III. rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 has been amended to recite "the endosomal lysing polymer of claim 1 or 5" as requested by the Examiner to avoid any ambiguity as to what polymer is being referred to. Applicant respectfully submits that the claim is now definite and requests that the rejection be removed.

In view of the forgoing amendments and arguments, Applicant respectfully submits that the present case is now in condition for allowance. A Notice to that effect is requested.

Please charge any fees that may be required for the processing of this Response, or credit any overpayments, to our Deposit Account No. 03-1721.

Respectfully submitted,

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7 of 13